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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,785	10/29/2001	Nedeljko Vladimira Gvozdic	MAC - 198	9527

7590 03/25/2004

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EXAMINER

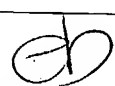
CHANG, VICTOR S

ART UNIT	PAPER NUMBER
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1771

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/020,785	Applicant(s) GVOZDIC, NEDELJKO VLADIMIRA	
	Examiner Victor S Chang	Art Unit 1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-91 is/are pending in the application.
 4a) Of the above claim(s) 1-3, 5-41 and 67-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 4, 42-66 and 77-91 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. The Examiner has carefully considered Applicants' amendments and remarks filed on 1/7/2004. Applicants' amendments to the specification, claims 4, 42, 47, 52, 57, 62, 77, 82 and 87 have been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Rejections not maintained are withdrawn. In particular, Applicant's argument that "the prior art teaches only the reinforcement of bulk polyvinyl alcohol hydrogels, not cellular polyvinyl alcohol hydrogels" (Remarks, page 3, first paragraph) has been fully considered and is persuasive, and the rejection in section 7 of Paper No. 1001 is withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 4, 42-66 and 77-91 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a reinforcing polyvinyl alcohol fibril, does not reasonably provide enablement for "a reinforcing material" as a genus. The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

More particularly, since the Specification only teaches a reinforcing polyvinyl alcohol fibril for reinforcing a cellular physically crosslinked polyvinyl alcohol matrix, the recitation in claim 4, line 6, "a reinforcing material" as a genus is considered to be too broad and in excess of provided enablement in the Specification. It should be noted that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice ... by functional characteristics coupled with a known or disclosed correlation between function and structure ... sufficient to show the applicant was in possession of the claimed genus. If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, first paragraph. See MPEP § 2163.IIA3(a)ii.

6. Claims 4, 42-66 and 77-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner repeats (see Paper No. 1001, page 5) that the claims are still replete with indefinite and functional or operative language. For example:

With respect to Applicant's response argues that "The Examiner has rejected claim 42, because of the use of the phrase "providing conditions". Applicant would state that this phrase is not vague and indefinite in that there is adequate information in the specification and especially in the examples to make a determination of what "providing

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conditions" means", it should be noted that although the claims are interpreted in light of the Specification, limitations from the Specification are not read into the claims. See *In re Van Geuns*, 988 f.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Clarification is requested.

In claim 42, lines 8-12, and throughout, the scope of the solvent virtually encompasses all the suitable solvents, as such it is clearly unnecessary to recite the solvents as two members in a Markush format. Simplification is suggested.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 4, 42-66 and 77-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 5 of U.S.

Patent No. 6608117 in view of its Specification, and further in view of Graiver et al. (US 5336551).

Claims 3, 5 of US '117 is directed to a method of preparing physically crosslinked cellular polyvinyl alcohol (PVA) hydrogels. In the specification, US '117 teaches that PVA hydrogel sponges made in the form of films and sheets can be reinforced with short or long fibers or woven or non-woven fabrics (i.e., laminates) fibrous materials (column 14, lines 11-13).

For claim 4, although US '117 lacks an express teaching of PVA fibrils being imbedded into the PVA hydrogels, it is noted that Graiver's invention is directed to a reinforced polyvinyl alcohol hydrogel containing uniformly dispersed reinforcing polyvinyl alcohol fibrils (Abstract). As such, it would have been obvious to one of ordinary skill in the art to incorporate the PVA fibrils of Graiver into the hydrogels of US '117, motivated by the desire to reinforce the mechanical strength of the hydrogels.

For product-by-process claims 42-46, it is noted that all the process steps are expressly disclosed by claim 3 of US '117 (column 18, lines 9-32).

For product-by-process claims 47-51, it is noted that all the process steps are expressly disclosed by claim 5 of US '117 (column 18, lines 62 to column 19, line 27).

For product-by-process claims 52-61, it is noted that all the process steps are expressly disclosed by claim 8 of US '117 (column 20, lines 11-35).

For product-by-process claims 62-66, it is noted that all the process steps are expressly disclosed by claim 10 of US '117 (column 20, line 57 to column 21, line 22).

For product-by-process claims 77-81, it is noted that all the process steps are expressly disclosed by claim 12 of US '117 (column 21, line 49 to column 22, line 23).

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For product-by-process claims 82-91, it is noted that all the process steps are expressly disclosed by claim 13 of US '117 (column 22, lines 23-58).

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In addition, the following references are cited of interest for making a polyvinyl alcohol porous body:

US 5502082 to Unger et al. is directed to a covalently crosslinked polyvinyl alcohol porous body.

US 6268405 to Yao et al. is directed to porous and solid physically crosslinked polyvinyl alcohol hydrogels for use in the replacement and augmentation of soft tissue or non-load bearing bones (Abstract).

10. The Examiner notes that Applicant fails to bring a related application 09/853517, now issued U.S. Pat. No. 6608117, to the Examiner's attention. It should be noted that while Applicant is not required to refer to applications which is not copending in an application data sheet or in the specification of the later filed application, but is required to otherwise call the examiner's attention to the earlier application if it or its contents or prosecution are material as defined in 37 CFR 1.56(b). See MPEP § 201.11. See also MPEP § 704.11(a).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DANIEL ZIRKER
PRIMARY EXAMINER
GROUP 1900

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